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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,794	07/15/2003	Ian L. Brown	28053/37955A	7883

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,794	BROWN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/23/03, 9/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 13 and 14 have been amended. Claims 13-25, 36 and 37 remain pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112

Claims 13-25, 36, and 37 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the previous Office action.

Applicant's arguments filed December 8, 2005 have been fully considered but they are not persuasive.

Applicant contends that one of ordinary skill would have measured resistant starch levels by the McCleary method, it being the only AOAC-approved method for such a measurement and goes onto discuss the use of the McCleary method, along with the Muir method, in other references cited in the specification. However, Applicant suggests that one of ordinary skill would look to Brown et al (Food Austr., 1995), which was cited in the specification. This reference cites Prosky et al (JAOAC, 1988) as providing "the officially accepted method of the Association of Analytical Chemists" for detecting resistant starch. So it is not clear to the examiner exactly what the Applicant's position is here: (1) One of ordinary skill would use any

AOAC-approved method; (2) One of ordinary skill would use any method disclosed in a reference cited in the specification; (3) Something else.

Applicant notes that "the McCleary and Muir methods give results which are within the accepted experimental error and thus are considered to be the same." It is possible that one of ordinary skill would construe a particular RS percentage recited in a claim to have an assumed experimental error built in because of the lack of precision seen in the various methods used in the art—for example, "20%" is interpreted to be "20% ± X%"—but this is not clear.

The examiner is not persuaded that at the time of the invention there was one accepted and standard method for the measurement of RS or that the instant specification clearly points to the use of any particular method. It is further noted that the Megazyme document, cited in the previous Office action discusses several methods used in the art. There is no mention of any particular industry standard. Finally, it is also noted that BENGS et al (WO 00/38537 – from Applicant's newly submitted IDS) uses the Englyst method to determine RS content. See Example 3.

Claim Rejections - 35 USC § 102

Claims 13, 16-19, 22, 23, 36, and 37 are again rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 96/08261) with McNAUGHT et al (WO 94/14342) to support inherency.

Claim 13 has been amended to require that the RS is present in a proportion of at least 20% by weight. BROWN uses the McCleary method to determine that the RS% is 18.1, with no margin of error disclosed. In other measurements disclosed in Table 3, the average margin of

error is about 2%. It is noted that McNAUGHT uses the Muir method—deemed equivalent to McCleary by Applicant—to determine RS value of 20% (+/- 1.8%) for what appears to be the same starch used in BROWN. Given the uncertainty of the metes and bounds of the range "at least 20%" as discussed above, it appears that the starch used in the BROWN composition is likely to fall in this range. The examiner does not agree that this amendment clearly avoids anticipation, as Applicant contends.

Claims 13, 14, 16-20, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by WIBERT et al (US 5,776,887) with SEIB (US 5,855,946) for inherency.

WIBERT discloses a drink comprising 3.3 g of a vegetable oil blend and 6.667 g of Novelose® a starch comprising 33% RS. (See SEIB at Table V.) This composition comprises RS in a proportion of about 22% by weight of the total carbohydrate content.

Claim Rejections - 35 USC § 103

Claims 13, 15-20, 22-25, 36, and 37 are again rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN et al (WO 96/08261) with McNAUGHT et al (WO 94/14342) to support inherency as discussed above.

Applicant's arguments filed December 8, 2005 have been fully considered but they are not persuasive.

Applicant argues that the reference offers no instruction to select unsaturated fats over saturated fats. In the absence of unexpected results, it would be within the scope of one of ordinary skill to select any of the components suggested. However, the artisan would be

particularly motivated to use the type of fat exemplified in the disclosed compositions. These comprise no fat or unsaturated fat.

Applicant further contends that the extrusion process teaches away from the invention but fails to provide the reasoning for this position.

Finally, Applicant argues that BROWN does not teach that this composition has utility for various methods such as regulation of carbohydrate and fat metabolism or reduction of obesity. However, Applicant's intended use is not a patentable limitation.

Claims 13, 14, 16-23, 36, and 37 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WIBERT et al (US 5,776,887) with SEIB (US 5,855,946) for inherency as above.

WIBERT teaches as set forth above. The reference does not exemplify a composition having an energy content as recited in claims 21-23. However, the reference specifically suggests the preparation of compositions that are "nutritionally complete" so that the composition contains adequate nutrients to sustain healthy human life for extended periods. See paragraph bridging col 5-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare compositions having adequate energy for part of or all of a patient's needs, as expressly suggested by the reference. One of ordinary skill would reasonably expect success in preparing such compositions.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Patent Examiner
March 3, 2006